



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/123,614	07/28/1998	LEE M. MIDDLEMAN	12032	5740

7590 10/18/2004

DAVID A. FARAH, M.D.
SHELDON & MAK
225 SOUTH LAKE AVENUE 9TH FLOOR
PASADENA, CA 91101

EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT	PAPER NUMBER
----------	--------------

3763

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/123,614

Applicant(s)

MIDDLEMAN ET AL.

Examiner

Cris L. Rodriguez

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 7-11, 22, 24-28, 32-47 and 60-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7-11, 22, 24-28, 32-47 and 60-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3763

DETAILED ACTION

1. In view of the Appeal Brief filed on July 29, 2004, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 7, 10, 11, 22, 24, 25, 28, 33-35, 60, and 61 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goldberg et al (US 5,152,777).

Art Unit: 3763

Goldberg discloses a device having a tubular element **70,72,74** with a hollow tubular lumen, a deployment element (stem **60,90**) (also considered as the guide wire set forth in claims 7, 40 and 50) having a lumen 62, and a plurality of resilient anchoring members **32A-32F** as claimed. The collar is reference numeral 38. In column 8 lines 23-66, it set forth that the deployment element(stem) has a lumen from proximal to distal end in order to introduce a guidewire or a marker solution into the body.

4. Claims 38-40, 44 and 45 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hayashi (5,910,144).

Hayashi discloses a prosthesis gripping system comprising a tubular element **20,26** comprising a hollow tubular lumen, a deployment element **50** (the guide wire set forth in claims 7, 40 and 50 is reference numeral 36), and a plurality of resilient anchoring members **40** as claimed. The collar is reference numeral **50**.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8, 9, 26, 36, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. in view of Abrams.

Goldberg discloses the invention substantially as claimed as discussed above. However, Goldberg fails to disclose the anchoring members being of a pseudo elastic

Art Unit: 3763

material such as nickel titanium alloy, or the anchoring members having an oval cross-section.

Abrams teaches a catheter apparatus comprising control wires having curved feet for anchoring purposes, made of nitinol, which is a pseudo elastic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg by providing the anchoring members with the materials of Abrams as taught old and well known in the art for anchoring purposes. Also, the oval cross-section is an obvious variation from the circular cross-section. The court have been held that the configuration of a claimed subject matter would have been a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed subject matter was significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al in view of Lefebvre (US 5,938,683).

Goldberg discloses the invention substantially as claimed as discussed above. However, Goldberg fails to disclose the anchoring members having a substantially flat top portion.

Lefebvre teaches a filter (anchoring member) comprising a substantially flat top portion for anchoring in a blood vessel (see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg by providing the anchoring members with the substantially flat top portion as

Art Unit: 3763

shown by Lefebvre to anchor the anchoring members to the passageway of a blood vessel and as an obvious design alternative.

8. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg in view of Hayashi as applied to claim 28 above, and further in view of Abrams.

Goldberg/Hayashi discloses the invention substantially as claimed as discussed above. However, Goldberg/Hayashi fails to disclose the anchoring members comprising a pseudo elastic material such as nickel titanium alloy.

Abrams teaches a catheter apparatus comprising control wires having curved feet made of nitinol, which is a pseudo elastic material for anchoring purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Goldberg in view of Hayashi by providing the anchoring members with the materials of Abrams as taught old and well known in the art for anchoring purposes.

9. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al in view of Hayashi as applied to claim 28 above, and further in view of Lefebvre.

Goldberg/Hayashi discloses the invention substantially as claimed as discussed supra. However, Goldberg/Hayashi fails disclose the anchoring members having a substantially flat top portion.

Lefebvre teaches a filter (anchoring member) having a substantially flat top portion for anchoring purposes in a blood vessel (see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

Art Unit: 3763

modify Goldberg/Hayashi by providing the anchoring members with the substantially flat top portion of Lefebvre to anchor the anchoring members to the passageway of a blood vessel and as an obvious design alternative.

10. Claims 41- 43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi in view of Abrams and Hayman et al.

Hayashi discloses the invention substantially as claimed as discussed above. However, Hayashi fails to disclose the anchoring members being of a pseudo elastic material such as nickel titanium alloy or made of spring steel, or the anchoring members having a substantially oval cross-section.

Abrams teaches a catheter apparatus having control wires having curved feet made of nitinol, which is a pseudo elastic material, and Hayman teaches an anchor 19 having arms 21 made of spring steel for anchoring purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Hayashi by providing the anchoring members with the materials of Abrams and Hayman as taught old and well known in the art for anchoring purposes. Also, the oval cross-section is an obvious variation from the circular-cross section.

11. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi in view of Lefebvre.

Hayashi discloses the invention substantially as claimed as discussed above. However, Hayashi fails to disclose the anchoring members having a substantially flat top portion.

Art Unit: 3763

Lefebvre teaches a filter (anchoring member) having a substantially flat top portion for anchoring purposes in a blood vessel (see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Hayashi by providing the anchoring members with the substantially flat top portion of Lefebvre to anchor the anchoring members to the passageway of a blood vessel and as an obvious design alternative.

Response to Arguments

12. Applicant's arguments filed July 29, 2004 have been fully considered but they are not persuasive.

13. In regards to applicant's arguments that Goldberg does not teach an inner lumen having a bore extending completely through the inner lumen, the examiner directs applicant's attention to Col. 8 lines 23-66. Lumen 62 extends from proximal (out of the patient) to distal end (inside the body).

14. In regards to applicant's arguments about Hayashi's device, it has all the elements as claimed and is capable of temporarily anchoring a passageway, as discussed in the rejection abovementioned.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (703) 308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 14, 2004


Cris L. Rodriguez
Examiner
Art Unit 3763